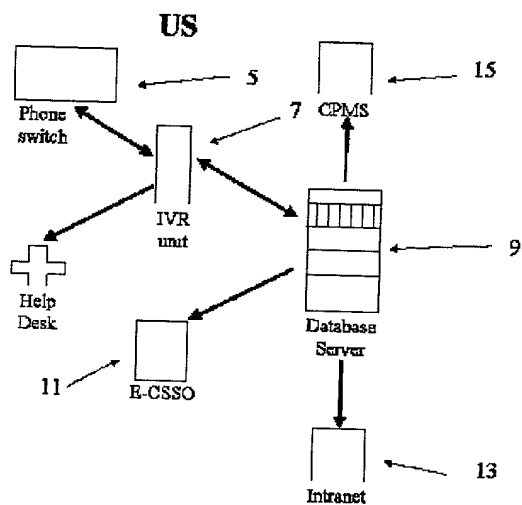


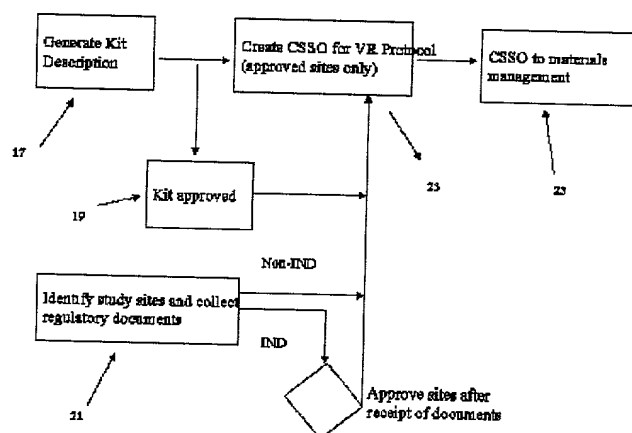
096641-07001
T00E20 T03T00000



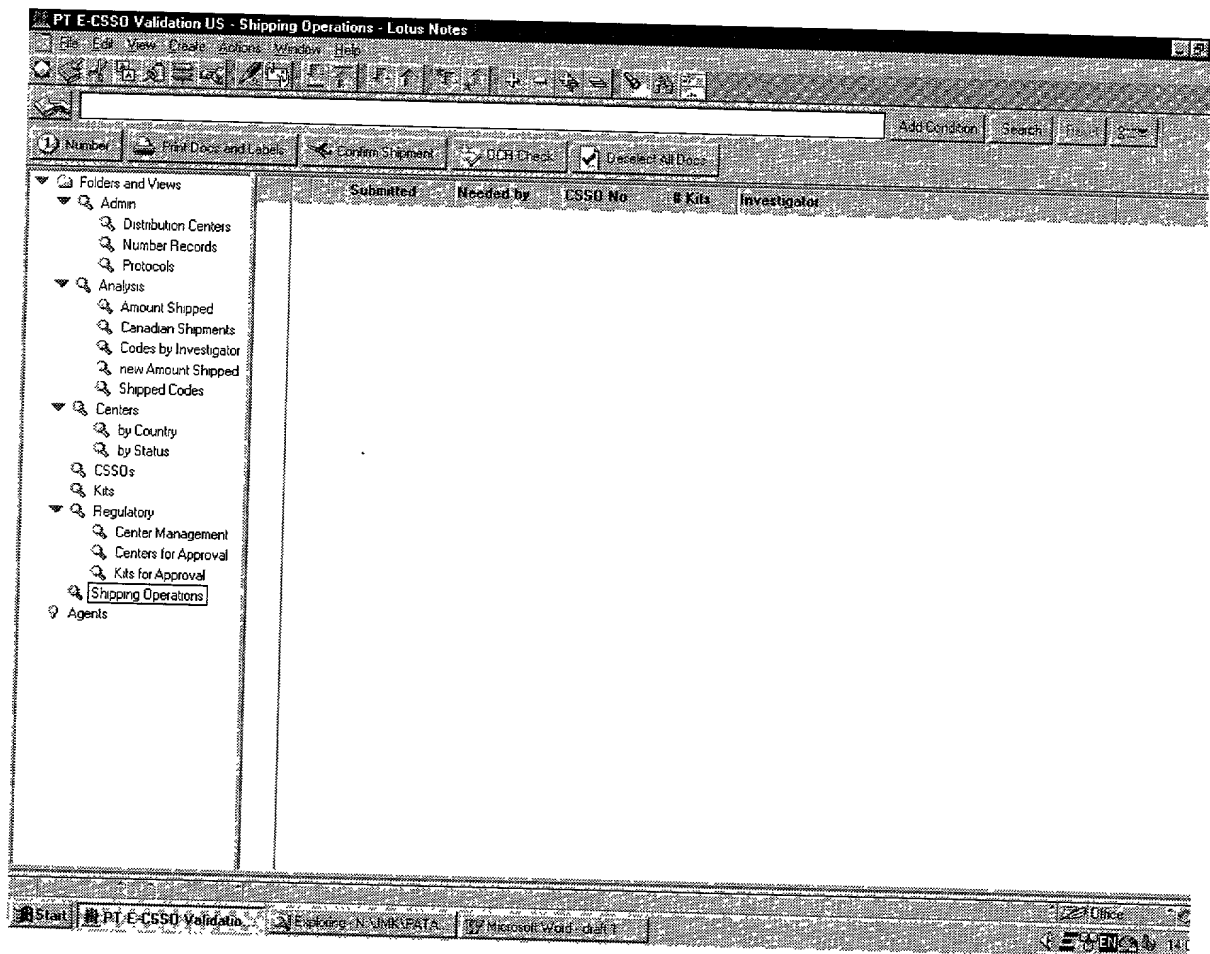
The diagram illustrates the relationship between traditional and virtual randomization in clinical trials. It is divided into three main sections:

- Traditional:** This section shows 8 Patient Kits, each containing 10 Bottles. The text "8 Patient Kits" is placed next to the kits, and "10 Bottles" is placed next to the bottles. The word "Containing" is placed between the kits and the bottles.
- Virtual randomization:** This section shows a large number of bottles, representing the virtual randomization process. The text "Virtual randomization" is placed above the bottles.
- 192 Bottles:** This section shows a large number of bottles, representing the total number of bottles in the trial. The text "192 Bottles" is placed next to the bottles.

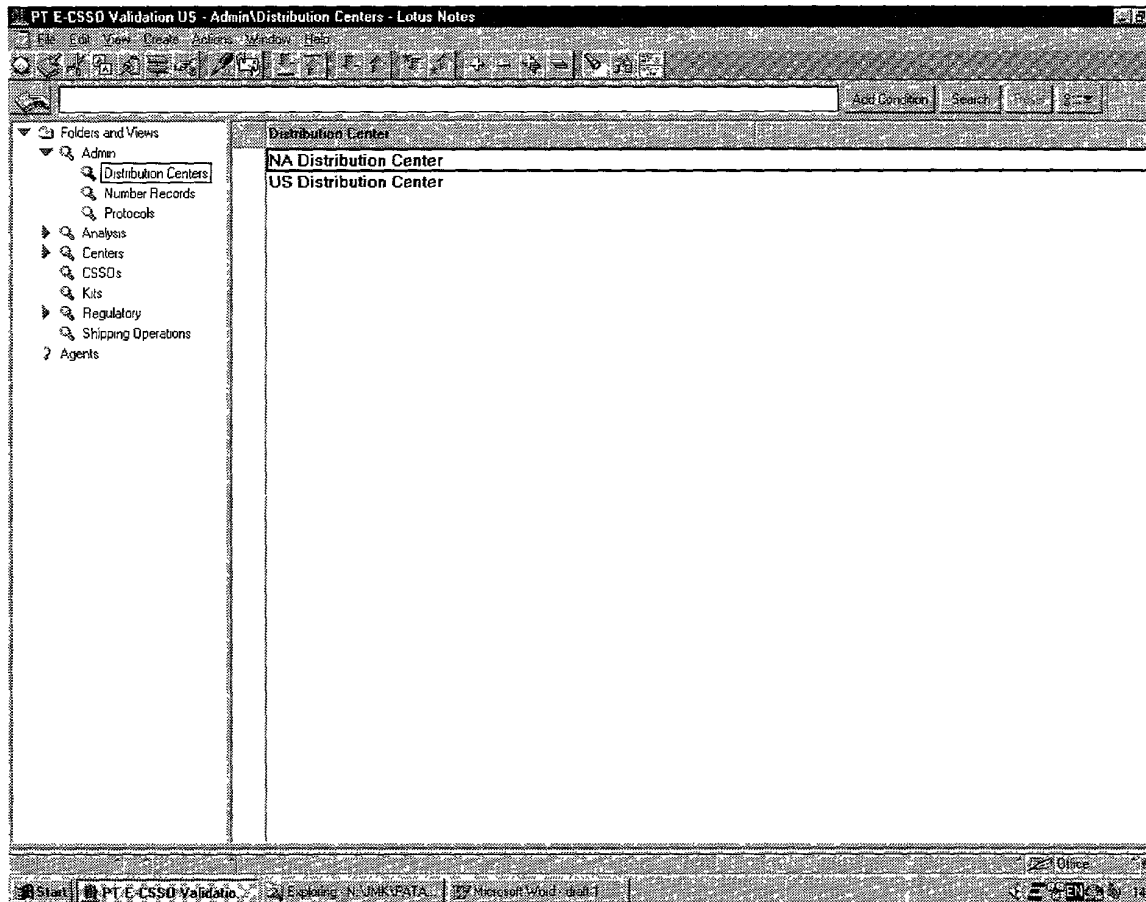
Figure 4

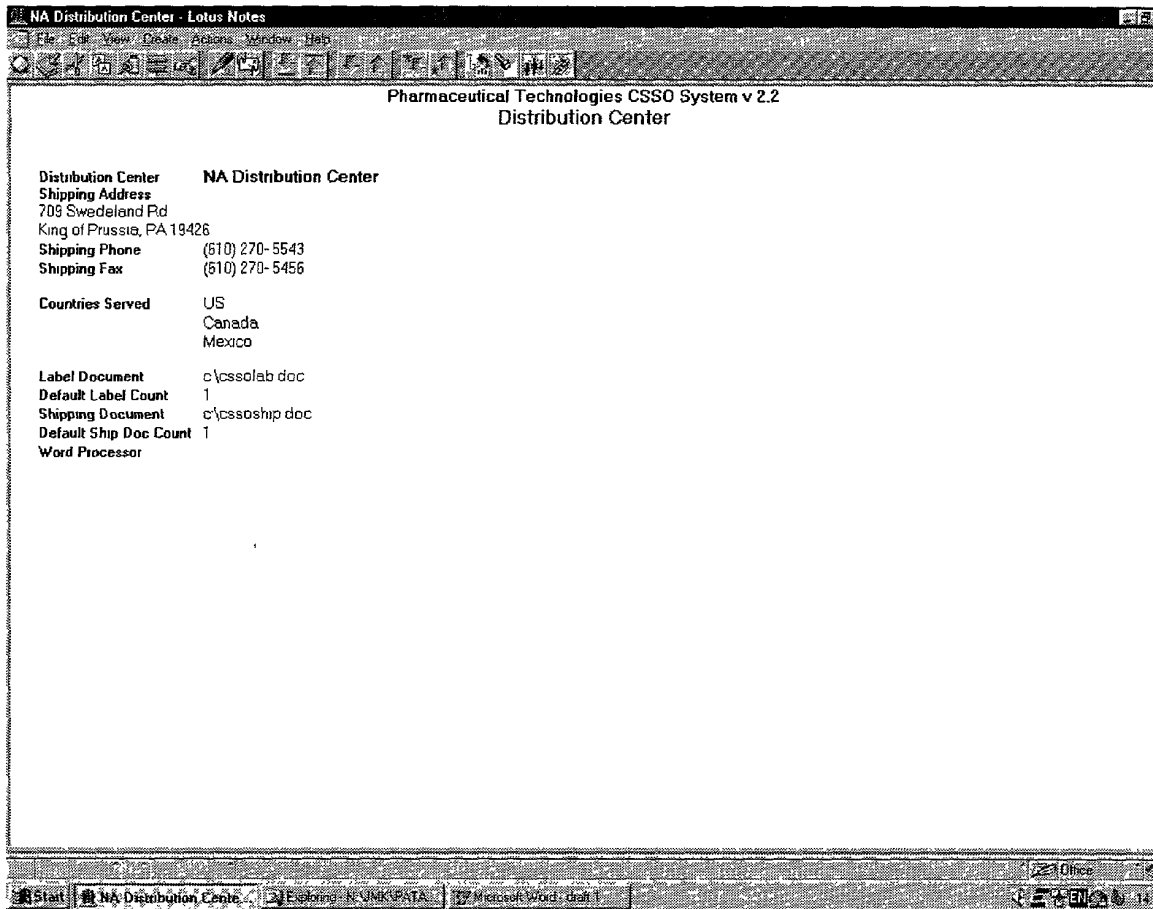


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Case 1:15-cv-01001-TPD





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100E20 1412960

PT E-CSSO Validation US - Admin\Protocols - Lotus Notes

File Edit View Create Actions Window Help

Search Add Condition

Folders and Views

- Admin
 - Distribution Centers
 - Number Records
 - Protocols**
- Analysis
- Centers
- CSSOs
- Kits
- Regulatory
- Shipping Operations
- Agents

Protocol	IND Study	IVH Study	Countries
111111			
001	Yes	No	US
002	Yes	Yes	US
222222			
001	No	No	Canada Mexico

Start PT E-CSSO Validation Exploring N:\NMV\DATA Microsoft Word - draft1

Protocol 222222/001 - Lotus Notes

File Edit View Create Address Window Help

Pharmaceutical Technologies CSSO System v 2.2
Clinical Protocol Definition

Project 222222
Protocol 001

IND Study No
IVR Study No

Participating Countries and Corresponding Distribution Centers

Countries	Distribution Centers
Canada	NA Distribution Center
Mexico	NA Distribution Center

Start Protocol 222222/001 Exploring N UMK/PASA Microsoft Word - eCSSO

2006-01-10 10:00

Kit 111111/001/004: Treatment (B) - Lotus Notes

File Edit View Database Actions Window Help

Pharmaceutical Technologies CSSO System v 2.2
CTS Kit Definition

☐ Click to work with this document

▼ Kit Identification Section

Project	111111
Protocol	001
Kit Number	004
Kit Name	Treatment (B)
For Countries	US
Kit Description	Bottles of 21, Batch U99022
Available?	Yes
Randomized Supplies?	Yes
Number of Codes/Kit	1
Attention Date/Note	01-Jan-2000
Use-By Date by Batch	
Job Number	
Packaging Notes	
Location in Warehouse	
Number of Kits Made	0

▼ Regulatory Information Section

▼ Document History Section

Start Kit 111111/001/004 Explorer: N:\UNIK\DATA Microsoft Word: oCSSO

09683161-003004
100620-13128860

2008-10-16 10:28:00

PT E-CSSO Validation US - Kits - Lotus Notes

File Edit View Create Actions Window Help

Add Condition Search

Kit Kit Name Countries

1 Draft

2 Awaiting Approval

3 Active

111111

001

001 Run In (A) US

002 Treatment (A) US

003 RUn In (B) US

CC2 Test Kit to confirm Job Number uptake on csso form US

002

001 Open Lable Supply US

222222

001

001 Run In (Bilingual) Canada Mexico

002 Treatment (Canada) Canada

003 Treatment (Mexico) Mexico

Admin

Distribution Centers

Number Records

Protocols

Analysis

Amount Shipped

Canadian Shipments

Codes by Investigator

new Amount Shipped

Shipped Codes

Centers

by Country

by Status

CSSOs

Kits

Regulatory

Center Management

Centers for Approval

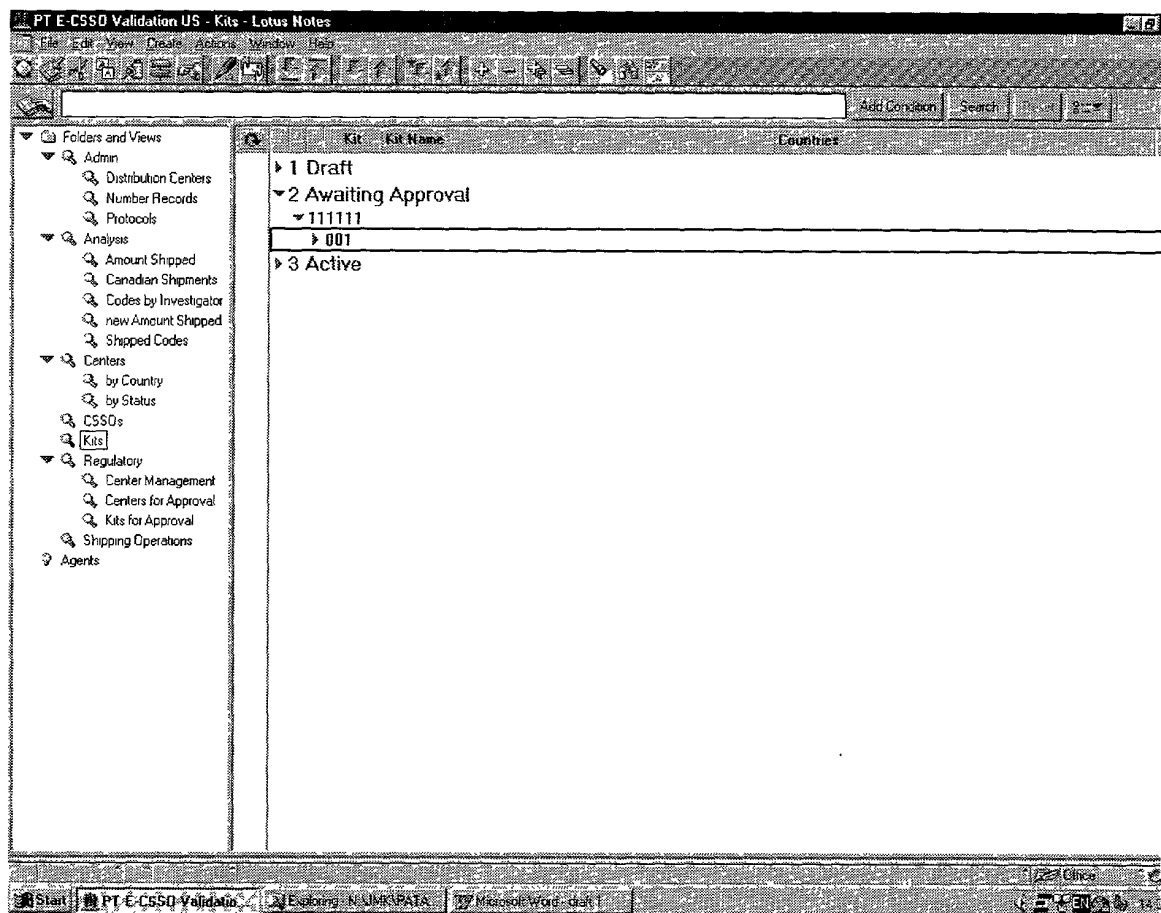
Kits for Approval

Shipping Operations

Agents

Start PT E-CSSO Validation Exploring N:\MKV\DATA Microsoft Word eCSSO


096315.073004
100270 19122950



Center 111111/001/001: Phillip A Adelman - Lotus Notes

File Edit View Database Actions Window Help

Pharmaceutical Technologies CSSO System v 2.2
Clinical Investigation Center

 Click to work with this document

▼ Center Identification Section

Project	111111
Protocol	001
Center number	001

▼ Center Information Section

Principal Investigator Phillip A Adelman
Co Principal Investigator Phillip A Adelman
Shipping Address
100 1st Avenue
Phoenixville, PA 19460
Country US

Shipping Phone (610) 917-9551
Shipping Fax (610) 917-9552
Investigator Fax (610) 917-9559

CRA
Supply Coordinator Frank Hetzel, Richard Kirsh

Comments

▼ Regulatory Information Section

IND Filing 02-Jan-1999, serial number 000001
Protocol Filing
Investigator Filing
1572 Signed

Start Center 111111/001/001 Explorer: NAUMK.PATA Microsoft Word - CSSO

000001-000001-000001

095015107001

PT E-CSSD Validation US - Centers by Country - Lotus Notes

File Edit View Create Actions Window Help

Add Condition Search

Activate Centers

▼ Folders and Views

- ▼ Admin
 - Q Distribution Centers
 - Q Number Records
 - Q Protocols
- ▼ Analysis
 - Q Amount Shipped
 - Q Canadian Shipments
 - Q Codes by Investigator
 - Q new Amount Shipped
 - Q Shipped Codes
- ▼ Centers
 - Q **by Country**
 - Q by Status
 - Q CSSDs
 - Q Kits
- ▼ Regulatory
 - Q Center Management
 - Q Centers for Approval
 - Q Kits for Approval
 - Q Shipping Operations
- ▼ Agents

Status	Center Name
	Canada
▶ 222222	
	Mexico
▶ 222222	
	US
▶ 111111	

Start PT E-CSSD Validation Exploring N:\NKP\DATA Microsoft Word - draft 1

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PT E-CSSO Validation US - Shipping Operations - Lotus Notes

File Edit View Database Actions Window Help

Number Print Docs and Labels Confirm Shipment OCB Check Deleted All Done

Submitted Needed by CSSO No Kits Investigator

US Distribution Center

111111

001

03-Aug-2000	Not assigned	6	John S Clayton, MD
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Start PT E-CSSO Validation Exploring NAMKIPATA Microsoft Word - draft 1